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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,577	03/12/2001	Herbert Schlachter	0147-0220P	5756

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,577	Applicant(s) SCHLACHTER, HERBERT	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-13, 17-19 and 22-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-13, 17-19, and 22-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Amendment received on October 23, 2003 is acknowledged. Claims 2-13, 17-19, and 22-40 are pending in this application. Claims 1, 14-16, and 20-21 stand cancelled.

Response to Amendment

Rejection of claims 2, 7, 9, 11, 17, 18, 19, 30-31, 34-35, 38-40 under 35 U.S.C. 102(b) as being anticipated by Abad (5538740) is withdrawn in view of the amendment filed on October 23, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Rejection of claims 2-9, 11, 13, 17-19, 22-35, and 38-40 under 35 U.S.C. 103(a) as being unpatentable over Hersh et al (5,667,791) is maintained.

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Hersh et al teach a topical composition for skin damage containing squalene, vegetable oil containing fatty acids, seaweed, green tea (epigallocatechin), Vitamin B, Vitamin C, glycopeptide zinc, Epidermal Growth Factor (amino acids), and water. Hersh teaches that zinc enhances the invention and that zinc oxide may function by healing properties on wounds. The zinc salt is contained in the amount of 0.001 to 8%. See column 9, lines 30-45.

Hersh et al do not exemplify zinc oxide in the composition.

Although Hersh does not exemplify zinc oxide in the composition, it is deemed obvious to one of ordinary skill in the art to look at the guidance provided by Hersh et al and incorporate zinc oxide in the composition. One would be motivated to do so since Hersh teaches the importance of the inclusion of zinc salts and that zinc oxide has healing properties. Therefore, one would be motivated to add zinc oxide into Hersh's therapeutic composition for skin damage for its healing skin wounds.

Response to Arguments

Applicant argues that Hersh does not disclose a working example, which incorporates zinc oxide. The applicant argues that Hersh does not teach at least one amino acid in pure form since selenomethionine is regarded as an amino acid derivative and thus is not in pure form. Lastly, it is argued that Hersh does not disclose a specific combination of amino acids in pure form, zinc oxide, and a SPS.

Applicant's arguments filed October 23, 2003 have been fully considered but they are not persuasive. Firstly, the examiner points out that the recitation of "pure form" is given its broadest reasonable interpretation. The term pure means that the amino acids

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are not mixed with other substances or the term means that the amino acids are isolated from the source it is obtained. The applicant is incorrect in the assertion that the recitation of "pure form" excludes amino acid derivatives since the term only speaks on the form the amino acids are present in the composition. This is further substantiated by the remarks of June 2003 wherein the applicant stated the "present invention discloses and claims amino acids that are added in pure form and not in the form of secretions comprising an arbitrary mixture of amino acids in combination with further substances." Lastly, the examiner points to page 7 of instant specification wherein the applicant states that amino acids and their derivatives are acceptable. Further, the applicant states, "the amino acids and their derivatives are preferably added in a pure form." Therefore, it is clear that the term is not meant to exclude amino acid derivatives.

Secondly the examiner points out that Hersh not only teaches an amino acid derivative, the composition also contains an epidermal growth factor (EGF). EGF is a 53 amino acid polypeptide (see column 13, line 33), which reads on "at least one amino acid". The examiner points out that the scope of "amino acids" encompasses amino acids derivatives and amino acid sequences.

In regards to the argument pertaining to zinc oxide, the examiner points out that in a obviousness rejection the prior art does not have exemplify the composition, otherwise it would be said that it anticipates the rejection. In an obviousness rejection, the prior art has to suggest the invention. In the instant case, the prior art's composition may not include zinc peroxide, however, on column 9, line 31 to column 10, line 6, Hersh clearly states, "In a preferred embodiment, the composition of the present may be

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enhanced by the addition of zinc salts. Zinc salts function by its healing properties on wounds, particularly zinc oxide." The reference further teaches that in clinical studies with zinc oxide, the addition of zinc as an ingredient promotes the healing of radiation induced skin damage. Therefore, the motivation to add the instant zinc to the reparative cream is to promote the healing of skin damaged skin since the composition is directed towards healing radiation induced skin damage. It is further pointed out that disclosed examples do not constitute a teaching away from the broader disclosure. See *In re Susi*. Further, a reference may be relied upon for all that it reasonably suggest to one of ordinary skill in the art, including nonpreferred embodiments.

Lastly, in regards to the specific combination of ingredients to yield a desired results, the examiner first points out that the claim language does not exclude other ingredients in the composition. Second, the examiner points out that Hersh teaches the same composition for the same method and the applicant has not provided any unexpected results.

Therefore the rejections are maintained.

Rejection of claims 2, 6-7, 9-12, 17-19, 28-31, and 34-40 under 35 U.S.C. 103(a) as being unpatentable over Hillebrand (5,296,500) is maintained.

Hillebrand teaches a method of regulating wrinkles with a topical composition containing water, glycerin, tocopherol, N-acetyl-L-cysteine, zinc oxide, and sodium hydroxide (example 4). The composition may contain conventional additives such as soybean saponins. See column 7, line 64. Zinc oxide is taught as a sunscreen agent and is generally included in the amount of 1-20%. See column 8, line 44 to column 9,

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line 50. The composition is rendered odorless by utilizing zinc salts incorporated in the amount of 0.001-10%. Zinc peroxide is taught as one of the useful zinc salts utilized.

See column 4.

Hillebrand does not exemplify a composition incorporating zinc peroxide and the plant substance.

Although, Hillebrand does not exemplify a composition containing zinc peroxide or the plant substance, it is deemed obvious to one of ordinary skill in art to look to the guidance provided by Hillebrand and incorporate the instant plant substance and peroxide. One would be motivated to do so since Hillebrand teaches the conventional use of saponins in the cosmetic art and in the composition. Further, Hillebrand teaches the suitability of zinc peroxide in the composition to mask the odor of the composition. Therefore, a skilled artisan would have a reasonable expectation of success and similar results.

Response to Arguments

Applicant argues that Hillebrand does not teach an amino acid in pure form since a derivative is disclosed. The applicant argues that the reference does not disclose zinc peroxide or a zinc salt. Applicant argues that the secondary plant substance is not exemplified. Lastly, it is argued that Hillebrand does not teach the specific combination of amino acids, zinc oxide, and SPS.

Applicant's arguments filed October 23, 2003 have been fully considered but they are not persuasive. The argument that the recitation "pure form" exclude derivatives has

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been addressed above. The examiner again points out that the scope of the "amino acids" encompasses amino acids derivatives.

In regards to the argument that SPS is not exemplified, the examiner points out that the rejection is made under obviousness rejection and does not have to exemplify the instant invention. The art has to suggest the instant invention, which it does. On column 7, lines 60-65, Hillebrand clearly teaches the incorporation of conventional additives such as EGF, essential oils, and soybean saponins. One would be motivated to utilize the additives since the prior art clearly states these are suitable additives and are commonly used in the art. In regards to the argument that the reference does not teach the pharmaceutically effective amount of the SPS, the examiner points out that the applicant is relying on a feature that is not claimed. It is again pointed out that disclosed examples do not constitute a teaching away from the broader disclosure. See *In re Susi*. Further, a reference may be relied upon for all that it reasonably suggest to one of ordinary skill in the art, including nonpreferred embodiments.

In regards to the argument that the zinc is utilized for another reason, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Therefore, the rejection is maintained.

Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

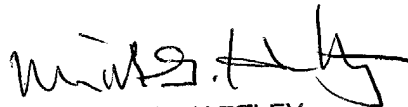
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147 or (571) 272-0614 after February 3, 2003. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG


MICHAEL G. HARTLEY
PRIMARY EXAMINER

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January 5, 2003